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(54) **I.V. catheter assembly with automatic cannula tip guard**

Venenkatheter mit automatischem Kanülenspitzenschutz

Cathéter intraveineux avec protection automatique de l'extrémité de la canule

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Description

BACKGROUND OF THE INVENTION

[0001] This invention relates to intravenous (I.V.) catheter assemblies and, in particular, to a catheter assembly having a cannula tip guard which automatically covers the cannula tip after use to prevent accidental injury from used cannulas.

[0002] Intravenous catheters for the infusion of fluids into the peripheral veins of a patient are one the most common devices used in I.V. therapy. In one type of catheter known as an over-the-needle catheter, the cannula and concentric outer catheter are inserted into the vein and the cannula is withdrawn through the emplaced catheter.

[0003] A typical over-the-needle I.V. catheter requires the user to remove and then dispose of a contaminated cannula after the cannula tip and catheter are properly located in the vein of the patient. Once the cannula is withdrawn from the catheter, the user's immediate priorities are infusion set connection and site preparation, including the taping of the catheter to the patient. Because of the urgency of these procedures the cannula is normally just dropped conveniently nearby and then retrieved later. Since the cannula at this time is exposed and located close to where the user is completing work with the catheter, accidental self-inflicted injuries are not uncommon. For reasons of the desirability of protecting the user from exposure to hepatitis and AIDS, there is an increasing need to protect the user from accidental cannula injury.

[0004] A catheter design which is directed toward this need is shown in U.S. Patent No. 4,762,516. The catheter shown in this patent includes an elongate body which houses a sliding needle guard. As the needle is withdrawn from the emplaced catheter, the user pushes the tab at the distal end of the needle guard, thereby sliding the needle guard out of the housing and along the needle, until the distal end of the guard covers the needle tip and the proximal end of the guard locks in the housing.. The needle and guard may then be set aside with the needle tip fully protected.

[0005] Another needle guard is shown in U.S. Patent 5,084,023. The needle guard in this patent includes a sleeve having a locking ring to secure the guard to a return valve assembly. The guard also includes a notch that engages a corresponding recess is the needle to prevent the needle from being withdrawn from the guard.

[0006] U.S. Patent 4,834,718 also discloses a needle tip guard. A hub portion of the guard of this patent mounts within the catheter hub and includes a resilient tongue. The tongue flexes outward to engage a recess in the catheter hub when the needle is inserted through the guard. When the needle is withdrawn into the guard, the tongue flexes inward releasing the guard from the hub. The guard is further comprised of a housing that extends the entire length of the blood chamber. A latching mechanism on the extreme end of the housing holds the needle tip within the guard.

[0007] While the arrangements described in the above prior art patents provide protection against accidental needle injury, the requirements of each of these devices necessarily requires rather long and/or bulky assemblies. Moreover, the arrangements are somewhat cumbersome to operate for users with small hands and fingers.

[0008] Accordingly, it would be desirable for a needle to be securely protected by a small needle guard,)and it would be most preferable for the needle guard to be moved into position over the needle tip automatically upon withdrawal of the needle from the patient, without the intervention of any special motion by the user.

[0009] US-A-4944725 provides an automatic needle guard fitted to a catheter assembly in which withdrawal of the cannula from the catheter results in the cannula being contained within a protective passage. However in order to prevent accidental reenergance of the cannula, a safety mechanism is provided to secure the cannula within the passage.

[0010] U.S. Patent 5,215,525 also discloses a needle guard. It comprises flexible fingers extending from a base. The fingers are resiliently biased to a closed position in which the tips are in contact. By withdrawing the needle into the needle guard, the tips contact together to secure the needle tip behind the contacting tips. In a second embodiment, the finger tips each comprise intermeshing saw tooth surfaces which can be snapped together with a latch lock to secure the needle tip behind the contacting tips.

SUMMARY OF THE INVENTION

[0011] The present invention is directed to a catheter assembly as defined in claim 1. In accordance with the present invention there is provided a catheter assembly comprising a catheter attached to the catheter hub. A cannula having a distal tip is insertable into the catheter through the catheter hub. A tip guard having a base and a plurality of resilient fingers extending from the base provides automatic protection against accidental needle sticks after withdrawal of the cannula from the catheter. In addition, locking means is provided for engaging the tip guard to the catheter hub when the cannula is inserted through the catheter hub. The locking means is adapted to release the tip guard from the catheter hub when the distal tip of the cannula is withdrawn from the catheter into the tip guard.

[0012] The plurality of fingers of the tip guard are spring biased to form a passageway from the base of the guard to the distal end of each of the fingers. The passageway has a diameter smaller than the diameter of the catheter. An addition, each of the fingers has a channel extending from the base to a location spaced from the distal end of the fingers. The finger channels

form a chamber having a diameter substantially equal to the diameter of the cannula. The fingers are adapted to flex radially outwardly to permit the cannula to be inserted into the catheter through the tip guard. The fingers return to the spring biased position when the distal tip of the cannula is withdrawn from the catheter into the tip guard thereby securing the distal tip within the chamber to prevent the distal tip of the cannula from being reinserted through the distal ends of the of the tip guard fingers.

[0013] The locking means is provided by a detent on the distal ends of the fingers and a corresponding recess in the catheter hub. When the fingers flex radially outwardly to permit the cannula to be inserted into the catheter hub, the detent on the fingers engages the hub in the recess. The thickness of the cannula causes the fingers to remain in that flexed position thereby locking the tip guard into the hub.

[0014] The catheter assembly further includes a cannula housing engaging the cannula on a proximal end of the cannula, a blood flash chamber attached to the cannula housing and a cannula guard. The cannula guard is attached to the tip guard and extends radially over only a portion of the cannula: Preferably, the cannula guard extends over less than half the circumference of the cannula permitting a low, oblique angle of insertion.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015]

Figure 1 is a schematic cross sectional view of the catheter assembly of the present invention.

Figures 2(a) and 2(b) are a side elevational and an end view of a tip guard not according to the present invention.

Figure 3 is a side elevational view of the tip guard shown in Figures 2A and 2B with the cannula inserted through the tip guard.

Figure 4 is a side elevational view of a tip guard of the present invention.

Figures 5, 6 and 7 are side elevational views of the tip guard of Figure 4 showing the insertion and withdrawal of a cannula.

Figures 8, 9, 10 and 11 are cross sectional views taken along the corresponding lines of the tip guard shown in Figure 4.

Figure 12 is a cross sectional view of one embodiment of the means for locking the tip guard into the catheter hub.

Figure 13 is a cross sectional view of the catheter hub of the catheter assembly of the present invention.

Figure 14 is and end view of the catheter housing of the catheter assembly of the present invention.

Figures 15 and 16 are cross sectional views of the housing taken along the corresponding lines of Figure 14.

Figures 17, 18 and 19 are cross sectional views of the housing taken along the corresponding lines shown in Figure 16.

Figures 20(a) and 20(b) are a side elevational view and an end view of the blood flash chamber and cannula guard of the catheter assembly of the present invention.

Figures 21, 22 and 23 are schematic views showing the operation of the catheter assembly of the present invention including insertion into a vein, withdrawal and protection by the tip guard.

DETAILED DESCRIPTION OF THE INVENTION

[0016] Referring now to the drawings, Figure 1 is a schematic side view of the catheter assembly 10 of the present invention. Catheter assembly 10 includes a catheter 12 attached to a catheter hub 14. Acannula 16 having a distal sharp tip 18 is insertable into the catheter 12 through the catheter hub 14. the catheter assembly 10 also includes a catheter housing 20 that engages a proximal end 22 of the cannula for insertion and withdrawal of the cannula into and out of the catheter 12. A blood flash chamber 24 is attached to the housing 20 and is sealed on its open end with plug 26. The catheter assembly 10 further includes a tip guard 28 and a cannula guard 30.

[0017] Figures 2(a), 2(b), and 3 show detailed views of one embodiment of a tip guard not according to the present invention. Tip guard 32 includes a plurality of resilient fingers 34 that extend from a base 36. The tip guard 32 also includes mounting flange 38 that rests against the catheter hub 14 and a portion 39 that attaches into the housing 22. Although two fingers 34 are shown in Figure 2 (a), it is understood that three or more fingers may be provided. The plurality of fingers 34 are spring biased so that the distal ends 40 of each of the fingers is in contact as shown at 42, thereby forming a closed chamber 44 within the tip guard 32. The fingers 34 are adapted to flex radially outwardly as shown in Figure 3 to permit the cannula 16 to be inserted into the catheter hub 14 through the tip guard 32. The fingers 34 are flexed radially outwardly by mechanical means such as angled jaws, wide enough to allow the cannula to pass through the tip guard with out touching the guard.

[0018] Each of the fingers 34 includes a detent 46 extending radially outwardly from each of the finger bodies 48. The detents 46 fit within corresponding recesses 50 in the catheter hub 14 when the cannula 16 is inserted through the tip guard 32 as shown in Figure 3. The combination of the detents 46 mating within recesses 50 and the flange 38 abutting hub 14 locks the tip guard 32 within the catheter hub 14. As shown in Figure 2(a), when the cannula 16 is withdrawn from the catheter such that the tip 18 is positioned within the chamber 44, the spring biasing of the fingers 34 causes the distal ends 40 to again contact each other at 42 with the cannula tip 18

secured within the closed chamber 44. Thus, the tip guard 32 provides both an automatic tip protection mechanism when the cannula is withdrawn from the catheter as well as an automatic locking mechanism for engaging the tip guard to the catheter hub when the cannula is inserted in the catheter. A gasket 52 is provided within the base of the tip guard for sealing the cannula within the tip guard.

[0019] Figures 4-11 show a tip guard of the present invention. As shown in Figure 4, tip guard 54 includes a plurality of fingers 56 extending from base 58 to their distal ends 60. The fingers 56 are spring biased to form a passageway 62 extending from base 58 to the distal ends 60 of each of the fingers. Each of the fingers 56 also includes a channel 64. The diameter 66 of the passage way 62 is smaller than the diameter 68 of the cannula 16. The combination of the channels 64 form a chamber 70 that has a diameter 72 substantially equal to the diameter 68 of the cannula 16. The fingers 56 also include detents 74 for locking into corresponding recesses in the catheter hub (not shown).

[0020] 5 As shown in Figure 5, the fingers 56 are adapted to flex radially outwardly to permit the cannula 16 to be inserted through the tip guard 54. As stated above, mechanical means such as angled jaws are used to flex the fingers radially outwardly sufficient to permit the cannula to pass through the tip guard without touching the fingers 56. As shown in Figure 6, after the cannula 16 is inserted through the tip guard 54 the fingers 56 are released from the angled jaws and spring back to contact the outer surface of the cannula 16. The fingers 56 in this position are slightly radially expanded thereby putting a slight spring tension on the cannula. This tension provides a snug fit but still permits the cannula to be inserted further into the catheter and withdrawn from the catheter through the tip guard 54. As shown in Figure 7, once the cannula 16 is withdrawn such that the tip is within the tip guard 54 the fingers 56 spring back to their original biased position. The cannula 16 then becomes secured within the chamber 70 formed by the channels 64. As can be seen in Figure 7, the passageway 62 is smaller in diameter than the outside diameter of the cannula 16 and is prevented from being reinserted through the distal ends 60 of the fingers 56. If reinsertion is attempted, the tip 18 will abut against the end walls 76 of the channels 64 and therefore cannot re-emerge from the tip guard 54.

[0021] Figure 8 is a cross sectional view of the tip guard 54 of Figure 4 taken along Lines 8-8. The distal ends 60 are shown with the passageway 62 having a diameter 66. Figure 9 shows a cross sectional view of the tip guard 54 of Figure 4 taken along Lines 9-9. Fingers 56 are shown with detents 74 protruding from the finger bodies for engaging the corresponding recesses in the catheter hub. Chamber 70 is shown which has a diameter 72 smaller than the diameter 66 of passageway 62. Figure 10 is a cross sectional view taken along Lines 10-10 of Figure 4 which shows the base 58 and includes a gasket 76 contained in a gasket well 78. The passageway 62 and channel 70 are visible through a central opening in the gasket 76. Figure 11 is a cross sectional view of a rear portion 80 of the tip guard 54 taken along lines 11-11 of Figure 4. A slot 82 is provided for attaching cannula guard 30 to the tip guard 54 by means of a press fit. The rear portion 80 in this embodiment is comprised of a U-shaped member having triangular ribs 81, which fit into complementary slots in housing 22.

[0022] As noted above, the detent on the fingers and the corresponding recess in the catheter hub provide the locking means to engage the tip guard to the catheter hub. The detent recess construction shown for example in Figure 3 has a relatively severe depth and angle. An alternative construction is shown in Figure 12 wherein a very shallow, rounded detent 84 and corresponding recess 86 are provided. For example, the detent and recess can be as small as .002 to .008 in depth. A shallow detent recess would simplify molding so that a straight pull and a simple mold for both the tip guard and the catheter hub can be used. In addition, a rounded design will allow the tip guard to be removed from the catheter hub prematurely with some force, if necessary, but would not easily be disengaged. In the mold for forming a rounded detent tip guard the undercut can be easily stripped by pulling the blades forming the core. Pulling these blades would leave a gap in the plastic that would allow easy ejection of the undercut.

[0023] Figure 13 shows a basic catheter hub 88 with the only difference between the standard hub and the hub utilized in the present invention is the recess 90. As with the tip guard, if a rounded recess is provided a straight pull in the mold could be used with no collapsing coils or special tooling.

[0024] Figures 14-19 show one embodiment of the catheter housing 20 shown in Figure 1. An end view of the housing 90 is shown in Figure 14. The cannula 16 runs through the center of the housing and the recess 92 is provided for receiving the blood flash chamber. Detents 91 and grooves 93 hold the cannula guard in place and together with slot 96 allow it to move forward and backward smoothly. Figure 15 is a cross sectional view of the housing 90 taken along Lines 15-15 of Figure 14. The passageway 94 is provided for inserting the cannula, and slot 96, as stated above, receives the cannula guard. Figure 16 is a cross sectional view of the housing 90 taken along Lines 16-16 of Figure 14. Stepped regions 98 provide finger holes where the user grips the housing in order to insert the cannula into the catheter and to remove the cannula from the catheter. Slots 100 receive ribs 81 on the tip guard. Figure 17 is a cross sectional view taken along Lines 17-17 of Figure 16 which shows slots 100 for receiving triangular ribs 81 holding the tip guard secure to the cannula guard. A hole 102 is provided to accept the blood chamber. Figure 18 is a cross sectional view taken along Lines 18-18 of Figure 16 which shows the hole 102, the detents 91 and

the grooves 93. Figure 19 is a cross sectional view taken along Lines 19-19 of Figure 16 which shows area 104 cut out to allow easy molding with no steel deflections.

[0025] While the tip guard will completely surround and encapsulate the sharp point or tip of the cannula, the cannula guard in accordance with another aspect of the present invention will only surround the shaft of the cannula on one side. This feature of the invention is shown in Figures 20(a) and 20(b). Figure 20(a) shows the cannula 16 partially extending within the blood flash chamber 24. The cannula guard 30 does not completely surround the cannula 16 or blood flash chamber 24 but only surrounds a portion of the cannula 16. In the preferred embodiment the cannula guard 30 surrounds less than half of the circumference of the cannula 16. Having the cannula guard only on one side of the cannula allows for a light, slim and trim catheter assembly that permits a low angle of insertion. Also shown in Figure 20(a) is the detent 105 that limits the forward movement of the guard with respect to the housing.

[0026] The catheter assembly of the present invention provides many advantages over the prior art. The collapsing nose design provides an automatic protection mechanism that protects the tip of the cannula irregardless of the insertion technique. In addition, the tip guard also provides an automatic locking of the guard to the catheter hub. The catheter assembly is slim, light and trim and allows for a very low, oblique angle of insertion. The assembly has a very large, long, flushable, easily seen blood flash chamber. Moreover, the palm of the hand is prevented from moving the catheter on the cannula during insertion. The user can see the cannula directly during insertion as there is clear material and/or a color difference between the cannula mechanism and the guard mechanism so that operation is intuitive. The catheter assembly of the present invention is inexpensive and simple to tool and mold as well as assemble. The one sided guard permits the blood chamber to be very large. In addition the blood chamber is longer than the cannula guard preventing accidental advancement.

[0027] In operation, as shown in Figure 21, the catheter assembly is initially provided with the cannula extended through the tip guard 28, catheter hub 14 and catheter 12. The catheter 12 and cannula 16 are initially inserted into the vein 106. Once the cannula 16 is inserted into the vein 106, blood will be observed filling the blood chamber 24 as indicated at 108. The cannula 16 can then be threaded into the vein 106, pushing or pulling on the catheter hub 14 or the cannula guard 30 as the catheter hub 14 is still locked to the tip guard 28. Once the catheter 12 is properly placed as shown in Figure 22, the cannula 16 is then removed from the catheter 12. The withdrawal of the cannula is controlled by the rearward movement of the housing which is limited by the detent 105 on the guard 30. When the cannula 16 passes into the tip guard 28, the fingers 48 collapse releasing the tip guard 28 from the catheter hub 14 automatically protecting the sharp tip 18 as shown in Figure 23. The catheter 12 and catheter hub 14 are left in the patient and the locked and protected catheter assembly is then disposed of.

[0028] While there have been described and illustrated an illustrative embodiment of the present invention, it will be apparent to those skilled in the art that variations and modifications are possible without deviating from the principle of the present invention which shall be limited solely by the scope of the claims appended hereto.

Claims

1. A catheter assembly (10) comprising:

a catheter (12) attached to a catheter hub (14);
a cannula (16) having a distal tip (18), said cannula (16) being insertable into said catheter (12) through said catheter hub (14);
a cannula guard (30);
a tip guard (32) having a base (58) and a plurality of resilient fingers (56) extending from said base (58), said plurality of fingers (56) being spring biased towards a closed position, said fingers (56) being adapted to flex radially outwardly to permit the cannula (16) to be inserted into said catheter hub (14) through said tip guard (32); and
locking means (74) engaging said tip guard (32) to said catheter hub (14) when the cannula (16) is inserted through said catheter hub (14), said locking means (74) being adapted to release said tip guard (32) from said catheter hub (14) when the distal tip (18) of the cannula (16) is withdrawn from said catheter (12) into said tip guard (32),

wherein:

due to the spring bias of the fingers (56), the fingers (56) return to the closed position when the distal tip (18) of the cannula (16) is withdrawn from the catheter (12) into the tip guard (32), the closed position of the fingers (56) securing the distal tip (18) behind the tip guard (32);
each of said fingers (56) has a channel (64) extending from the base (58) to a location spaced from the distal end (60) of each finger (56);
the fingers (56), when biased into the closed position, define a passageway (62) extending from the distal end (60) of each finger (56) to the location spaced from the distal end (60) of each finger (56), said passageway (62) at the distal end (60) of the fingers (56) having a diameter smaller than the diameter of the cannula (16), thereby securing the distal tip (18) with-

in the chamber; and
the channels (64) of each finger (56) form the chamber which extends from the passageway (62) to the base (58), the chamber having a diameter substantially equal to the diameter of the cannula (16).

2. A catheter assembly (10) according to claim 1, wherein said locking means includes a detent (74) on the distal ends (60) of said fingers (56) and a corresponding recess (50) on the catheter hub (14).

3. A catheter assembly (10) according to claim 1 or claim 2, further including a cannula housing (20) engaging said cannula (16) on a proximal end of the cannula (16) and a blood flash chamber attached to said cannula housing (20).

4. A catheter assembly (10) according to any one of claims 1 to 3, wherein said cannula guard (30) is attached to said tip guard (32).

5. A catheter assembly (10) according to any one of claims 1 to 4, wherein said cannula guard (30) extends radially over a portion of said cannula (16).

6. A catheter assembly (10) according to claim 5, wherein said cannula guard (30) extends radially over less than half of the circumference of the cannula (16).

Patentansprüche

1. Katheterbaugruppe (10) mit:

   - einem Katheter (12), der an einer Katheternabe (14) angebracht ist;

   - einer Kanüle (16) mit einer distalen Spitze (18), wobei die Kanüle (16) durch die Katheternabe (14) hindurch in den Katheter (12) einsetzbar ist;

   - einem Kanülenschutz (30);

   - einem Spitzenschutz (32) bestehend aus einem Grundkörper (58) und einer Vielzahl elastischer Finger (56), die sich von dem Grundkörper (58) aus erstrecken, wobei die Vielzahl von Fingern (56) in Richtung einer geschlossenen Stellung federnd vorgespannt sowie in radialer Richtung nach außen biegbar ist, um das Einsetzen der Kanüle (16) durch den Spitzenschutz (32) hindurch in die Katheternabe (14) zu ermöglichen; und

   - einer Rasteinrichtung (74), mit welcher der Spitzenschutz (32) in die Katheternabe (14) eingreift, wenn die Kanüle (16) durch die Katheternabe (14) hindurch eingesetzt wird, wobei die Rasteinrichtung derart angeordnet ist, daß der Spitzenschutz (32) von der Katheternabe (14) gelöst wird, wenn die distale Spitze (18) der Kanüle (16) vom Katheter (12) in den Spitzenschutz (32) zurückgezogen wird; wobei

   - die Finger (56) infolge ihrer federnden Vorspannung in eine geschlossene Stellung zurückkehren, wenn die distale Spitze (18) der Kanüle (16) aus dem Katheter (12) in den Spitzenschutz zurückgezogen wird, wobei die distale Spitze (18) durch die geschlossene Stellung der Finger (56) hinter dem Spitzenschutz (32) gehalten wird;

   - jeder der Finger (56) einen Kanal (64) aufweist, der sich von dem Grundkörper (58) zu einer von dem distalen Ende (60) jedes Fingers (56) entfernten Stelle erstreckt;

   - die Finger (56), wenn sie in der geschlossenen Stellung vorgespannt sind, einen Durchlaß (62) begrenzen, welcher sich von dem distalen Ende (60) jedes Fingers (56) zu der von dem distalen Ende (60) jedes Fingers (56) beabstandeten Stelle erstreckt, wobei der Durchlaß (62) an dem distalen Ende (60) der Finger (56) einen Durchmesser hat, der kleiner als der Durchmesser der Kanüle (16) ist, wodurch die distale Spitze (18) innerhalb der Kammer gehalten wird; und

   - die Kanäle (64) jedes Fingers (56) die Kammer bilden, die sich vom Durchlaß (62) bis zum Grundkörper (58) erstreckt und einen Durchmesser aufweist, der im wesentlichen gleich dem Durchmesser der Kanüle (16) ist.

2. Katheterbaugruppe (10) nach Anspruch 1, bei welcher die Rasteinrichtung auf den distalen Enden (60) der Finger (56) einen Vorsprung (74) sowie eine entsprechende Vertiefung (50) an der Katheternabe (14) aufweist.

3. Katheterbaugruppe (10) nach Anspruch 1 oder 2, welche weiterhin ein Kanülengehäuse (20), welches die Kanüle (16) an einem proximalen Ende derselben umfaßt, und eine an dem Kanülengehäuse (20) angebrachte Blutstrahlkammer aufweist.

4. Katheterbaugruppe (10) nach einem der Ansprüche 1 bis 3, wobei der Kanülenschutz (30) am Spitzenschutz (32) angebracht ist.

5. Katheterbaugruppe (10) nach einem der Ansprüche

1 bis 4, wobei sich der Kanülenschutz (30) in radialer Richtung über einen Teil der Kanüle (16) erstreckt.

6. Katheterbaugruppe (10) nach Anspruch 5, wobei sich der Kanülenschutz (30) in radialer Richtung über weniger als die Hälfte des Umfangs der Kanüle (16) erstreckt.

Revendications

1. Ensemble formant cathéter (10) comprenant :

un cathéter (12) fixé sur un raccord de cathéter (14) ;
une canule (16) ayant une pointe distale (18), ladite canule (16) pouvant être insérée dans ledit cathéter (12) par l'intermédiaire dudit raccord de cathéter (14) ;
une gaine de canule (30) ;
une gaine de pointe (32) ayant une base (58) et une pluralité de doigts élastiques (56) s'étendant à partir de ladite base (58), ladite pluralité de doigts (56) étant inclinée au moyen d'un ressort vers une position fermée, lesdits doigts (56) étant adaptés pour fléchir radialement vers l'extérieur afin de permettre à la canule (16) d'être insérée dans ledit raccord de cathéter (14) par l'intermédiaire de ladite gaine de pointe (32) ; et
des moyens de verrouillage (74) mettent en prise ladite gaine de pointe (32) et ledit raccord de cathéter (14) lorsque la canule (16) est insérée à travers ledit raccord de cathéter (14), lesdits moyens de verrouillage (74) étant adaptés pour dégager ladite gaine de pointe (32) dudit raccord de cathéter (14) lorsque la pointe distale (18) de la canule (16) est retirée dudit cathéter (12) dans ladite gaine de pointe (32), dans lequel
en raison de l'inclinaison des doigts (56) au moyen d'un ressort, les doigts (56) reviennent dans la position fermée lorsque la pointe distale (18) de la canule (16) est retirée du cathéter (12) dans la gaine de pointe (32), la position fermée des doigts (56) fixant la pointe distale (18) derrière la gaine de pointe (32) ;
chacun desdits doigts (56) présente un canal (64) s'étendant à partir de la base (58) vers un emplacement éloigné de l'extrémité distale (60) de chaque doigt (56) ;
les doigts (56), lorsqu'ils sont inclinés dans la position fermée, définissent un passage (62) s'étendant à partir de l'extrémité distale (60) de chaque doigt (56) vers l'emplacement éloigné de l'extrémité distale (60) de chaque doigt (56), ledit passage (62) au niveau de l'extrémité distale (60) des doigts (56) ayant un diamètre inférieur au diamètre de la canule (16), fixant ainsi l'extrémité distale (18) à l'intérieur de la chambre ; et
les canaux (64) de chaque doigt (56) forment la chambre qui s'étend du passage (62) à la base (58), la chambre ayant un diamètre sensiblement égal au diamètre de la canule (16).

2. Ensemble formant cathéter (10) selon la revendication 1, dans lequel lesdits moyens de verrouillage comprennent un encliquetage (74) sur les extrémités distales (60) desdits doigts (56) et une cavité correspondante (50) sur le raccord de cathéter (14).

3. Ensemble formant cathéter (10) selon la revendication 1 ou la revendication 2, comprenant en outre un logement de canule (20) enclenchant ladite canule (16) sur une extrémité proximale de la canule (16) et une chambre de séparation du sang fixée audit logement de canule (20).

4. Ensemble formant cathéter (10) selon l'une quelconque des revendications 1 à 3, dans lequel ladite gaine de canule (30) est fixée à ladite gaine de pointe (32).

5. Ensemble formant cathéter (10) selon l'une quelconque des revendications 1 à 4, dans lequel ladite gaine de canule (30) s'étend radialement au-dessus d'une partie de ladite canule (16).

6. Ensemble formant cathéter (10) selon la revendication 5, dans lequel ladite gaine de canule (30) s'étend radialement au-dessus de moins de la moitié de la circonférence de la canule (16).

FIG. 1

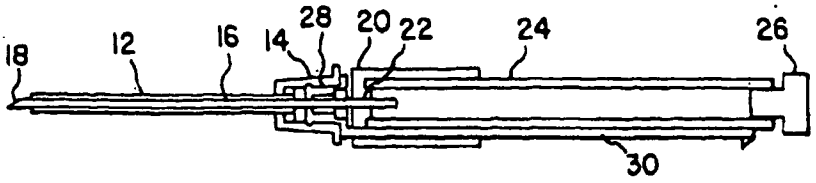


FIG. 2B

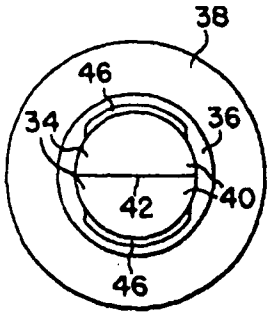


FIG. 2A

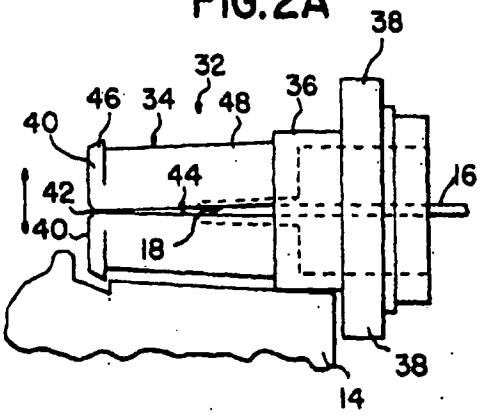


FIG. 3

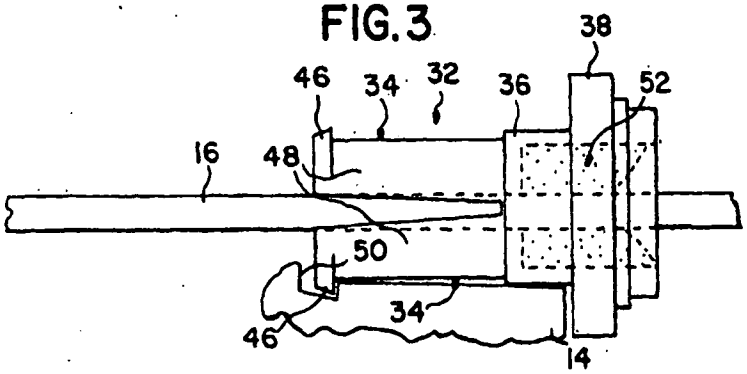


FIG.4

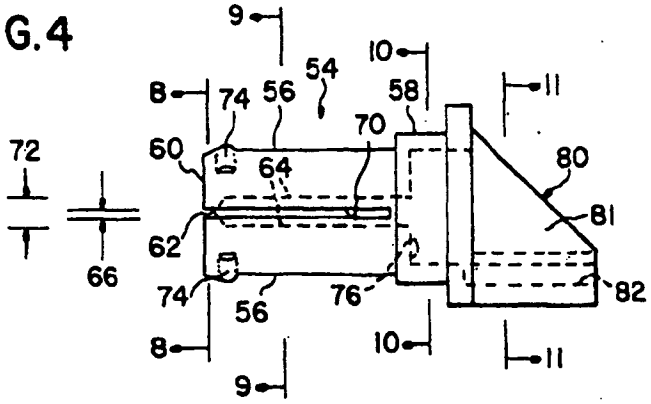


FIG.5

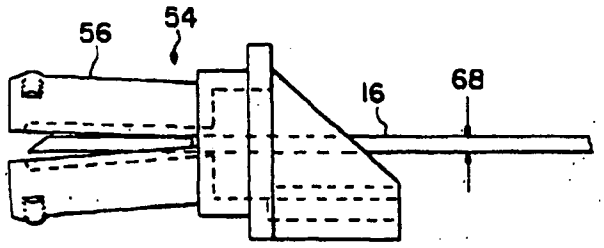


FIG.6

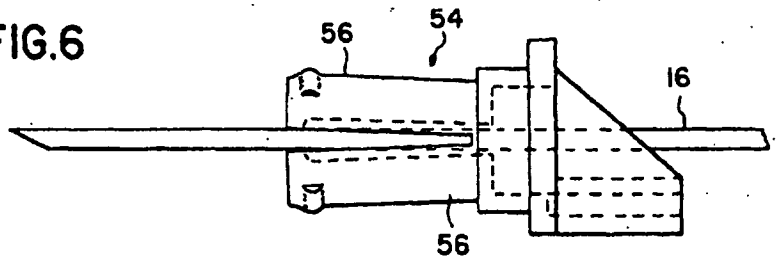


FIG.7

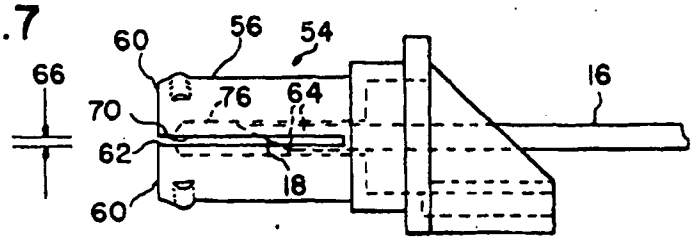


FIG. 8

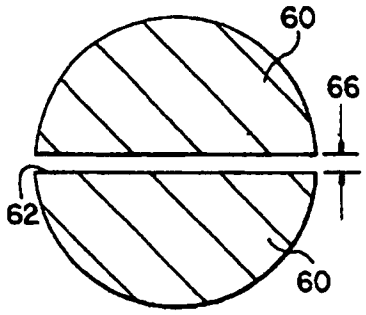


FIG. 9

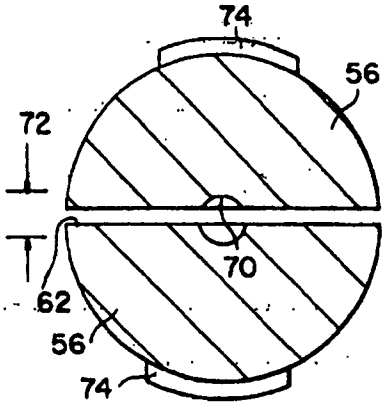


FIG. 10

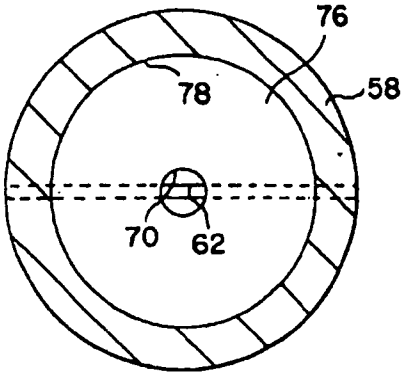


FIG. 11

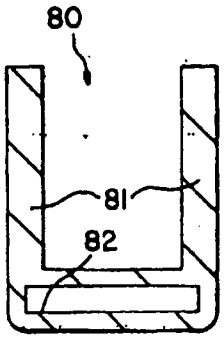


FIG. 12

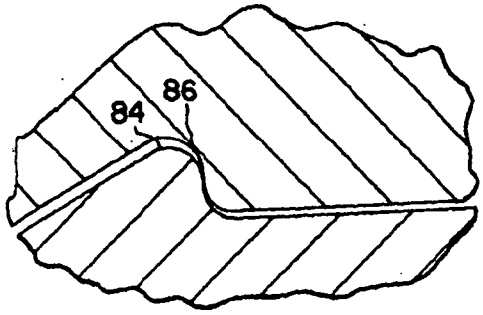


FIG. 13

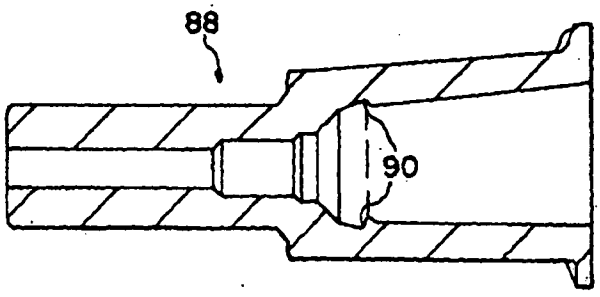


FIG.14

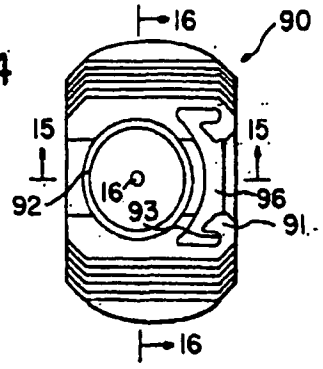


FIG.15

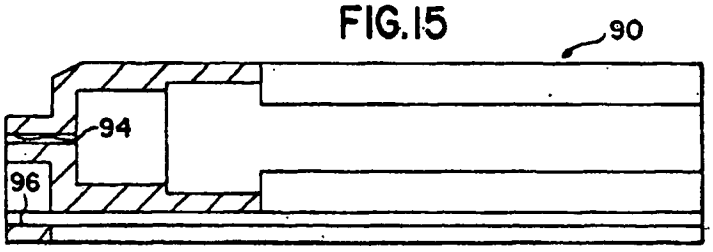


FIG.16

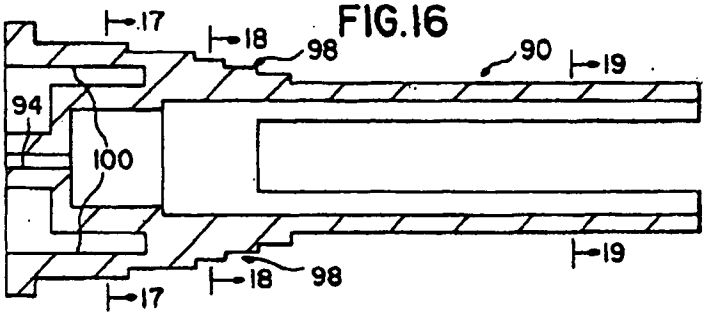


FIG.17

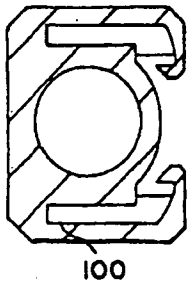


FIG.18

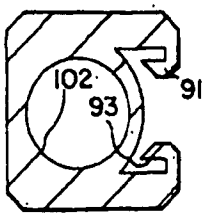


FIG.19

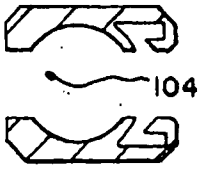


FIG.20A

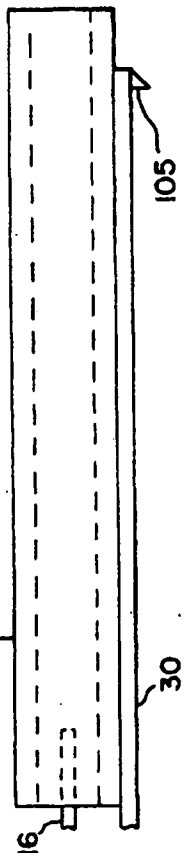


FIG.20B

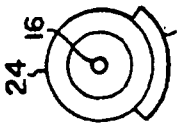


FIG.21

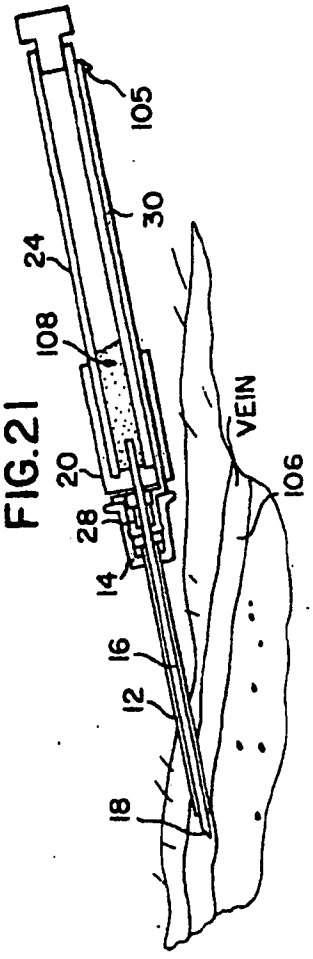


FIG.22

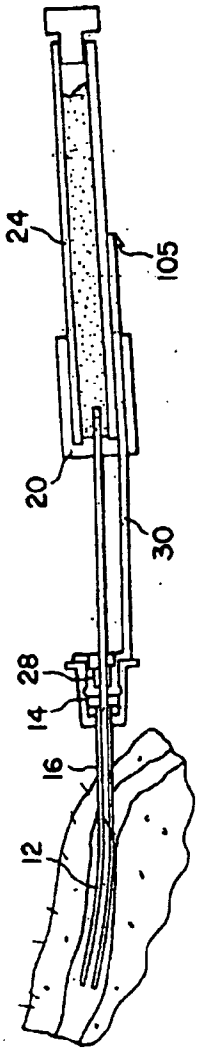
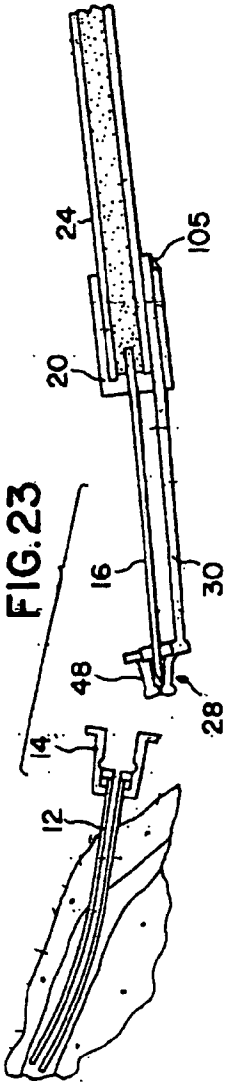


FIG.23



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GERMANY

YOUR REF

OUR REF O002541EP/CPM/RMC/alg

29th May 2002

Dear Sirs,

Re: European Patent No. EP0747085
Application No. 96304208.0
In the name of Johnson & Johnson Medical, Inc.

In response to the Summons to Oral Proceedings dated 28th January 2002, I enclose an Auxiliary Request for this case.

Amendments

In the Auxiliary Request, the features of claim 3 from the main request (main claim 3) have been incorporated into claim 1. Further, the "diameter" referred to in main claim 1 is now directed towards the chamber, rather than the channel. Further, claim 2 has been deleted.

Article 123(2)

It is believed that the Opposition Division will have no difficulty in accepting that these auxiliary claims clearly meet the requirements of Article 123(2) EPC.

Please note, however, that it is submitted that the claims from the main request also meet the requirements of Article 123(2) EPC. A skilled person, from reading the original application, would have considered the application as filed to disclose not just the individual embodiments therein, but also various combinations of the features of the two embodiments. From these combinations, the skilled person would readily consider the features of main claim 2 to be inherently disclosed in the original disclosure. Further, the interchanging of the term "channel" for the term "chamber" with respect to the diameter thereof makes no discernible difference to the scope of the claim, and it is submitted that

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To: **European Patent Office**
Fax No.:

the present language could therefore be maintained. However, if the Opposition Division cannot accept the present language, the proprietor would, as a further auxiliary request, be willing to make an amendment to the main request to change the language of the claim to that which the Opposition Division would allow, for example, as found in the relevant part of claim 1 of the attached claims for the first auxiliary request.

Article 54 and 56

O1

In each request, claim 1 requires a cannula guard. O1 does not disclose such a feature. Further, it is submitted that it goes way beyond the abilities of an ordinary skilled person to take the disclosures of O1 to arrive at an assembly having both a tip guard and a cannula guard. A complete redesign of the product in O1 would be required in order to arrive at anything close to the present invention, and this would only have been done in hindsight. Any obviousness arising merely through hindsight is not grounds for holding a claim not to meet the requirements of Article 56 EPC. It is submitted, therefore, that all the proposed claims 1 are not just novel, but also inventive over O1.

O2

The present invention requires the chamber or the channels to have a diameter substantially equal to the diameter of the cannula. This cylindrical section for the chamber of the channels results in the fingers conforming to the side walls of the cannula, thereby securing or holding the cannula more efficiently and tightly within the chamber than that achievable in any of the products disclosed in O2.

A skilled person would have had no reason to adopt such a construction for their assembly. Only upon seeing the success of that construction as shown by the present invention would the construction be adopted. It is therefore again submitted that the Opposition Division is merely finding obviousness in hindsight. For this reason it is submitted that the present invention is also both novel and inventive over the disclosures of O2.

Yours truly,

Mercer, Christopher Paul
(Carpmaels & Ransford Professional Association No. 162)

Enc. Auxiliary Request